SMEET SOLANKI

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PROFESSIONAL SUMMARY

Biomedical Engineer with hands-on experience in both industry and clinical settings, specializing in the design, validation, and maintenance of medical devices and diagnostic systems. Proven track record contributing to the development of cutting-edge technologies, including a robotic breast biopsy platform and breath-based cancer detection systems. Skilled in preventive maintenance, design verification, root cause analysis, and regulatory compliance under ISO 13485, ISO 14971, and FDA 21 CFR Part 820. Adept at collaborating with cross-functional teams, including clinicians, engineers, and quality professionals, to ensure patient safety, device performance, and regulatory readiness. Passionate about advancing healthcare through innovative engineering solutions that directly impact lives.

WORK EXPERIENCE

Biomedical Engineer | *Breathe BioMedical* – Moncton, NB Feb 2023 - Present

- Designed, assembled and validated **breath-based diagnostic medical devices** including the *Breath Sampler* and *Spectrometer*, ensuring precision alignment of internal airflow pathways, sensor housings, and filter retention components to meet design and clinical specifications.
- Designed and modified custom components using **SolidWorks** and **Fusion 360**, including sorbent tube holders, temperature indicator mounts, and thermal test fixtures, with emphasis on manufacturability and ergonomic integration.
- Maintained and updated the **Bill of Materials (BOM)** for multiple prototype and production assemblies, tracking part revisions, sourcing details, and ensuring version control in alignment with engineering change orders.
- Conducted **tolerance verification** of machined parts using digital calipers and engineered jigs, confirming compliance with ±0.1 mm tolerances per technical drawings.
- Led **root cause investigations** for anomalies such as condensation buildup, sorbent contamination, and thermal indicator failures, contributing to **CAPA documentation** in compliance with **ISO 13485** and **GMP standards**.
- Developed and executed **validation protocols** for Zebra LIMITmarker 18°C temperature indicators, simulating freeze-thaw and elevated temperature cycling, with high-frequency thermal monitoring using calibrated IR thermometers (±0.2°C resolution).
- Conducted seal integrity testing of Tenax sorbent tubes under methanol vapor exposure, validating the effectiveness of PTFE dust caps, Viton O-rings, and Swagelok end fittings through multi-day exposure trials and chemical analysis using **GC-MS**.
- Authored and maintained detailed **Design History File (DHF)** documents including protocols, experimental logs, validation summaries, and deviation reports to support internal audits and regulatory submissions.
- Performed **preventive maintenance** and **calibration** of lab instruments including vacuum ovens, IR thermometers, spectrometers, and cold storage systems to ensure experimental reproducibility and equipment readiness.
- Collaborated cross-functionally with Clinical, R&D, and Quality teams to deliver on-site training, provide technical support at clinical sites, and collect user feedback for device usability improvements.

Product Quality Engineer | *Abbott Laboratories* – Toronto, ON Sept 2021 - Feb 2023

- Supported the deployment, performance monitoring, and quality assurance of Alinity laboratory diagnostic systems across multiple hospital and reference lab sites, ensuring minimal downtime and adherence to global quality standards.
- Conducted **root cause investigations** into field complaints, including instrument malfunctions, software errors, and recurring service events; collaborated cross-functionally to implement **corrective and preventive actions (CAPA)** in compliance with **FDA 21 CFR Part 820** and **ISO 13485**.
- Maintained and contributed to **product quality records**, including non-conformance reports, service bulletins, and field action documentation using internal quality management systems (QMS).
- Interpreted system logs, service data, and site feedback to identify trends in component failures and signal processing anomalies, leading to effective containment actions and escalations to global engineering.
- Assisted in the **revision of the Bill of Materials (BOM)** for critical subassemblies based on field service feedback and replacement part traceability; helped ensure part consistency and traceability across regions.
- Collaborated with regional service engineers and manufacturing teams to provide feedback on product design limitations, proposing improvements in **component robustness**, **system calibration**, and **field serviceability**.
- Utilized **SolidWorks** to review and interpret component drawings, tolerances, and material specs during failure analysis and component traceability reviews.
- Supported **installation and verification** of updated hardware and software across clinical sites, ensuring system performance met post-market regulatory expectations.
- Delivered technical training and support to clinical users and biomedical technicians, improving frontline issue resolution and reducing support ticket volume.
- Acted as a liaison between field teams and corporate quality groups to relay real-world usage data and initiate product improvement discussions during global quality reviews.

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WORK EXPERIENCE CONTINUED

Medical Device Developer | *Libang Surgical Technologies* - Vancouver, BC April 2020 - Sept 2021

- Contributed to the design and development of a **robotic breast biopsy system**, supporting the integration of electromechanical subsystems for automated tissue sampling with a focus on precision, safety, and user ergonomics.
- Created and iterated 3D models of mechanical subassemblies using **SolidWorks** and **Fusion 360**, including needle actuation mechanisms, sensor housings, and frame mounts, ensuring alignment with design inputs and anatomical constraints.
- Conducted **tolerance analysis** and **mechanical fit testing of components**, ensuring manufacturability and compliance with **ISO 2768 standard** tolerances for medical instrumentation.
- Supported system integration, working with engineers and software developers to synchronize robotic actuation, user interface commands, and real-time sensor feedback to ensure functional alignment and responsiveness.
- Participated in **design verification and validation (DV&V)** efforts, including **bench testing**, **risk analysis (FMEA)**, and prototype evaluation to meet **early-stage ISO 13485** and **IEC 60601** development requirements.
- Assisted in the development of test protocols and experimental setups to measure needle insertion precision, alignment consistency, and mechanical repeatability in simulated use scenarios.
- Contributed to risk management activities in accordance with **ISO 14971**, identifying hazards related to over-insertion, motion faults, and device-user interactions, and proposed design mitigations.
- Supported the creation and organization of **Design History File (DHF)** components including test reports, engineering change records, and traceability matrices to prepare for future regulatory submissions.
- Collaborated closely with clinical advisors and surgeons to gather user feedback on robotic workflow, setup time, and usability, integrating insights into iterative design improvements.
- Participated in interdisciplinary engineering meetings to align timelines, review design milestones, and resolve cross-functional integration issues in a fast-paced start-up environment.

Biomedical Engineer Intern | *McMaster Children's Hospital* - *Hamilton, ON* Sept 2018 - April 2022

- Supported the maintenance, calibration, and performance testing of neurodiagnostic equipment, including EEG systems, EMG units, patient monitors, and infusion devices, under the supervision of clinical engineering staff.
- Conducted **electrical safety testing** using **Fluke biomedical analyzers** to assess leakage current, grounding continuity, and power integrity, ensuring compliance with **CSA Z32** and hospital safety standards.
- Participated in **preventive maintenance audits**, reviewed service logs, and verified calibration dates to identify high-priority devices requiring immediate attention.
- Helped investigate instances of EEG signal interference, performing outlet grounding checks, power line analysis, and assisting in mitigation planning with clinical and facilities staff.
- Assisted in updating and verifying the hospital's **equipment inventory database** using a **CMMS (Computerized Maintenance Management System)**, tagging over 400 assets for traceability and regulatory audit readiness.
- Collaborated with biomedical technologists to inspect, test, and validate the readiness of emergency neurology carts, ensuring critical diagnostic tools were fully operational and properly stocked.
- Collected and synthesized user feedback from EEG technologists and nurses regarding equipment usability, pain points, and maintenance concerns; contributed to a report that influenced procurement discussions.
- Supported the documentation of service activities, non-conformances, and inspection results in alignment with **Health Canada**, **CSA**, and **Accreditation Canada** clinical engineering protocols.
- Gained practical exposure to **risk mitigation**, incident reporting workflows, and the basics of **corrective/preventive actions (CAPA)** for hospital-based biomedical systems.
- Worked in a fast-paced, multidisciplinary environment, building communication skills while interfacing with **clinical teams**, **external service vendors**, and hospital administrators.

EDUCATION

Master of Engineering (M.Eng) 2022 - 2023
Biomedical Engineering - specializing in Engineers in Scrubs (EiS)
The University of British Columbia - Vancouver, BC

Honours Bachelor of Science (B.Sc) 2017 - 2022
Life Sciences - specializing in Neuroscience & Biomedical Devices
McMaster University - Hamilton, ON