SMEET SOLANKI

Yellowknife, NWT | 647-632-8791 | smeet.solanki1387@hotmail.com | www.LinkedIn.com/in/smeetsolanki

PROFESSIONAL SUMMARY

Biomedical Engineer with experience in medical device development, quality engineering, and process validation across regulated environments. Proven track record in developing and executing validation protocols for sterilization, cleaning, manufacturing processes, and equipment qualification in compliance with GMP, ISO 13485, and FDA 21 CFR Part 820. Skilled in applying risk management principles (FMEA, hazard analysis), authoring test methods, and driving cross-functional collaboration to support product and process verification. Experienced with design controls, defect tracking, and regulatory audits. Passionate about advancing neurotechnology and improving human health through rigorous quality systems and innovative problem-solving.

WORK EXPERIENCE

Provincial & Territorial Medical Device Manager | *Gov. of Northwest Territories* - NWT Aug 2025 - Present

- **Develop and maintain quantifiable Quality KPIs** (e.g., CAPA aging, deviation cycle time, training completion, document overdue rate, audit action closure) and **publish real-time/near real-time dashboards** using tools such as **Excel** / **Power BI** / **Google Sheets** / **Grafana** to enable leadership visibility and faster decision-making.
- Drive process improvements to strengthen **systemic compliance** and **quality standards**, applying creative problem-solving to simplify workflows, reduce rework, and improve right-first-time performance across cross-functional stakeholders.
- Support deviation and audit findings management by logging, triaging, assigning owners, tracking due dates, facilitating follow-ups, and **coordinating timely closure** with clear evidence of completion and effectiveness.
- Own and administer key subsets of the Quality Management System aligned to **ISO 13485** and **FDA 21 CFR 820**, ensuring procedures are followed, records are complete, and readiness is maintained for internal/external audits.
- Managing training matrices, onboarding/role-based curricula, competency tracking, overdue escalations, and training effectiveness documentation for staff and external partners/vendors where applicable.
- Control SOPs/work instructions/forms, manage versioning and approvals, enforce document retention and access, and coordinate change requests with impact assessments and implementation tracking.
- Initiating and managing CAPAs from trends/audits/issues, support root cause analysis (**5 Whys/Fishbone**), define corrective/preventive actions, track execution, and document effectiveness checks.

Biomedical Engineer | *Breathe BioMedical* - Moncton, NB Feb 2023 - Aug 2025

- Led process validation efforts for temperature-sensitive breath sampling devices, designing and executing test methods to evaluate performance across cleaning, sealing, and thermal stability protocols in compliance with **GMP and ISO 13485 standards**.
- **Developed and validated cleaning verification protocols** using swab sampling, microbial culture, and UV tracer visualization to ensure surfaces met stringent cleanliness and biocompatibility requirements.
- Designed and executed sterilization feasibility studies and dry-heat exposure protocols to assess indicator performance and ensure compatibility of materials with proposed sterilization methods.
- **Authored and executed** Installation, Operational, and Performance Qualification **(IQ/OQ/PQ)** protocols for equipment including temperature chambers, IR thermometers, and environmental monitors, ensuring regulatory compliance and traceability.
- Conducted risk assessments using **FMEA** to evaluate impact of design and process changes on product performance and validation status, contributing to robust design controls and process risk mitigation.
- Created and maintained **real-time dashboards** using **Google Sheets and custom scripting** to track environmental exposure trends and validation results, streamlining defect tracking and enabling proactive decision-making.
- Collaborated cross-functionally with R&D, Quality, and Regulatory Affairs to translate experimental findings into actionable updates in the **Design History File (DHF)** and **Device Master Record (DMR)**.
- Performed **root cause investigations** and supported **CAPA activities** for equipment malfunctions and validation failures, ensuring timely resolution and documentation in accordance with **FDA 21 CFR Part 820**.
- Supported early-stage software and hardware testing by designing custom validation test plans for breath sampler interfaces, ensuring alignment with **design inputs and regulatory expectations**.

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WORK EXPERIENCE CONTINUED

Product Quality Engineer | *Abbott Laboratories* - *Toronto, ON/Remote* Sept 2021 - Sept 2023

- Led process validation activities for critical manufacturing and cleaning operations, developing and executing **IQ/OQ/PQ protocols** to ensure equipment and systems met **GMP**, **ISO 13485**, and **21 CFR Part 820** requirements.
- Developed and validated test methods for product verification and packaging integrity using precision instruments and statistical sampling plans, ensuring consistent product quality and regulatory compliance.
- **Assessed the impact of design and process changes** on existing validations through documented risk evaluations and verification activities, supporting **design control** and **change management** processes.
- Conducted thorough **root cause investigations** for non-conformances and manufacturing deviations using **5 Whys**, **Fishbone Diagrams**, and **FMEA**, leading cross-functional **CAPA implementation** and process improvement initiatives.
- **Utilized Minitab** and **Excel-based SPC dashboards** to monitor critical process parameters and control charts, identifying trends and enabling real-time defect tracking across production batches.
- Participated in **internal and supplier audits**, supporting documentation reviews and gap analysis to maintain quality system robustness and readiness for **regulatory inspections**.
- Contributed to the development of automated defect tracking systems and implemented visualization tools for dashboarding key validation **KPIs**, improving response time and cross-functional communication.
- Interfaced with R&D, Regulatory Affairs, and Manufacturing teams to support validation strategy development, risk mitigation, and continuous improvement across multiple product platforms.
- **Authored validation reports and technical justifications** for equipment upgrades, re-qualification requirements, and risk-based testing strategies, ensuring traceability and audit-readiness.

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

- Led verification and validation testing of an early-stage robotic-assisted breast biopsy system, developing and executing **custom test methods** to evaluate needle actuation precision, force calibration, and material compatibility.
- Collaborated with cross-functional teams including mechanical, software, and clinical engineers to **define design inputs and outputs**, ensuring alignment with **design control requirements** per ISO 13485 and FDA 21 CFR Part 820.
- Developed and maintained validation protocols for mechatronic subassemblies and sensor integration systems used in real-time targeting and tissue acquisition under operating room conditions.
- **Performed risk assessments (e.g., FMEA, hazard analysis)** to evaluate device safety, usability, and failure modes, contributing to the creation of the **Risk Management File** in accordance with **ISO 14971**.
- Contributed to equipment and software qualification efforts by testing embedded microcontroller interfaces and motor drivers, supporting both functional and regulatory validation strategies.
- Conducted bench testing, preclinical simulations, and dry-run surgical trials using tissue analogs to validate system performance, generate traceable test reports, and inform iterative design improvements.
- **Documented validation results** in DHF-compliant technical reports, providing justifications for design acceptance criteria and test strategy modifications based on engineering judgment and observed outcomes.
- Supported early-stage usability and human factors testing to assess interface design, user interaction pathways, and system alerts, aligning device functionality with surgical workflow requirements.
- Participated in regulatory submission preparation by providing verification data and validation evidence supporting Class II medical device development.

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

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WORK EXPERIENCE CONTINUED

Medical Device Developer | *Libang Surgical Technologies (cont.)* - *Vancouver, BC/Remote* April 2020 - Sept 2021

- Developed and maintained validation protocols for mechatronic subassemblies and sensor integration systems used in real-time targeting and tissue acquisition under operating room conditions.
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Biomedical Engineer Intern | *McMaster Children's Hospital* - *Hamilton, ON* Sept 2018 - April 2022

- Supported the verification and calibration of clinical equipment, including infusion pumps, ventilators, and physiological monitors, ensuring functionality aligned with hospital SOPs and **CSA/ISO safety standards**.
- Assisted in the execution of preventive maintenance and performance checks for critical care devices, documenting procedures and results in the hospital's **CMMS system**, improving traceability and uptime.
- Conducted incoming inspection and functional validation of new biomedical devices prior to clinical use, verifying operational parameters and flagging inconsistencies for corrective action.
- Collaborated with Clinical Engineering Technologists to identify recurring equipment issues and performed root cause analysis for malfunction trends, contributing to **CAPA reports** and process improvements.
- Participated in equipment risk assessment meetings to evaluate device hazards and help determine appropriate control measures, increasing awareness of patient safety and compliance with **Health Canada and ISO 14971**.
- Assisted with developing and revising SOPs and technical work instructions to align with updated hospital protocols and ensure compliance with **TJC and provincial biomedical guidelines**.
- Gained hands-on exposure to GMP and regulatory-compliant hospital practices, observing the integration of engineering judgment in healthcare environments and the importance of robust **quality management systems (QMS)**.
- Communicated effectively with clinical staff during device troubleshooting scenarios, ensuring minimal disruption to care delivery and reinforcing safety protocols in high-pressure settings.

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 in Engineering (BSE) 2017 - 2022
Biological Engineering (Co-op)
***McMaster University* - Hamilton, ON**