MERIN GRACE

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EDUCATION

Cornell University, Weill Cornell Graduate School of Medical Science — NEW YORK, NY
Masters in Biostatistics and Data Science — **August 2020 (Expected)**

- Key coursework in R, Python, SAS

The City College of the City University of New York (CCNY) — NEW YORK, NY
Bachelor of Engineering in Biomedical Engineering — **August 2012 – May 2016**

- Key coursework in Circuits, Image & Signal Processing, Biomedical Transducers & Instrumentation, Cell & Tissue Mechanics, Neural Engineering, Nanomaterials

WORK EXPERIENCE & JOB HISTORY

STRYKER — MAHWAH, NJ
Sr. Engineer, Risk Management — **February 2019- Present**

- Analyze large sets of Post Market data to evaluate performance of various joint replacement products and present the results of trend analysis to management and external regulatory agencies for decision making.
- Create Risk Tables for various types of hip and knee Joint Replacement products.
- Collaborate with cross-functional teams for remediation of outdated Risk documentation to ensure compliance with EU MDR.

Sr. CAPA Analyst — **August 2017 – February 2019**

- Monitor and generate monthly trending reports using big datasets regarding CAPA performance as shown through corporate Key Process Indicators (KPIs) and present data-driven insights to stakeholders.
- Responsible for the management and facilitation of Non-conformances & CAPA activities across cross-functional departments to ensure timeliness, effectivity, and regulatory compliance.
- Regularly performed gap analysis of all CAPA-related procedures and processes to ensure alignment between regulatory regulations and all global functional sites including corporate.
- Represented all quality teams during any internal and external audits regarding CAPA records and procedures.
- Collaborated with global partnered sites to streamline CAPA procedures to reduce waste.
- Led technical training sessions to provide guidance on Root Cause & Problem Solving Methodologies.
- Cross-trained and assisted the Regulatory Department in filing Medical Device Reports.

SOTERIX MEDICAL INC. — NEW YORK, NY
Quality Control Engineer — **June 2016 – August 2017**

- Responsible for testing and verification of design & performance of Transcranial Direct Current Stimulation (tDCS) Class II Neural Stimulation medical devices.
- Managed product related nonconformances and process deviation requests with compliance to domestic and international regulatory authorities.
- Maintained device history records (DHR) of all the products and conducted periodic reviews of the digital DHRs and Device Master Records (DMR).
- Tested device platforms to ensure design assurance on parts that are in new product development phase including key design input, devices features, and functions.
- Authored testing documents for new products to ensure adequate testing of design features.
- Supervised and trained entry Quality Engineers in device verification and validation.

Manufacturing Engineer (Intern) — **June 2014 – June 2016**

- Responsible for manufacturing various types of brain stimulation devices such as multichannel tDCS, double blind, and animal stimulation medical devices.
- Worked cross-functionally to test new design platforms of advanced multichannel brain stimulation devices.
- Utilized Ultiboard and Multisim to design trigger system circuitry for multichannel stimulation devices.
- Trained interns in soldering PCB boards, manufacturing and debugging devices.

ENGINEERING RESEARCH & PROJECTS

ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI, & CCNY NEW YORK, NY

Cerebrospinal Fluid (CSF) Spinal Motion Phantom (Senior Design Project) **2015 – 2017**

- Researched, designed, and manufactured the prototype of a MRI compatible dynamic spinal motion phantom that mimics the anatomy of spinal canal, fluid dynamics of cerebrospinal fluid (CSF) of the human spine.
- Continued to work post-graduation and developed an improved version of the spinal phantom in coordination with Mount Sinai Hospital, focusing in depth on anthropomorphic and material properties, simulating B0 inhomogeneity and the T1, and T2 relaxation times.

Abstract (International Society for Magnetic Resonance in Medicine (ISMRM))

- Seifert, A., Patel, V., Grace, M., Li, R., Molla, M., Borrello, J., Xu, J. November 2016. Anthropomorphic Spinal Cord Phantom with Induced Field Inhomogeneity. International Society for Magnetic Resonance in Medicine 25th Annual Meeting and Exhibition, Honolulu, HI

CERTIFICATION & SKILLS

Technical skills

- Matlab, R, Python, SAS, SolidWorks, TrackWise, Tableau, Power BI, Leankit, Corel Draw, ImageJ, Multisim, Ultiboard, Circuit Analysis, Oscilloscope, MS Office (Excel, Word, PowerPoint, Outlook, Visio), MacOS/Windows

Certifications

- Six Sigma Certification – White Belt