

Marquette degreed Biomedical Engineer with four years of experience in the medical device industry. Eager to bring education, thinking, and people skills to the right organization to support the right team's business development goals.

People Oriented	• Natural ability as a communicator and people connector
Detail Oriented	• Thinks analytically with optimism and creativity
Bilingual	• Fluent in English and Spanish
Learning	• Constantly looking at best practices, best ways, best options
Finance	• Natural affinity to numbers
Persistence	• Commitment to results and goals

EXECUTIVE HIGHLIGHTS & CHRONOLOGY

Quality Engineer II

September 2021 - January 2022

Bio-Rad Laboratories, Hercules, CA (Remote)

- Performed quality reviews on CAPA files and approved them for closure
- Compiled and analyzed information to identify unacceptable trends and benefit-risk conclusions with the goal of driving suitable corrective actions needed to maintain safe and effective products
- Facilitated risk management activities by updating and maintaining risk management files

Post-Market Surveillance Specialist

September 2020 - September 2021

ACIST Medical Systems, Eden Prairie, MN (Remote)

- Analyze product complaints holistically and make critical judgments on potential reportability of adverse events to global regulators
- Assist in preparing correspondence to global regulatory agencies requests for additional information
- Facilitate the progress of complaints throughout the complaint lifecycle to ensure proper documentation and timely closure of each complaint

Quality Engineering Analyst

April 2019 - May 2020

Cook Polymer Technology (CPT), Bloomington, IN

- Improved CPT's quality management system deficiencies surrounding complaint processing, manufacturing procedures, root cause analysis, and corrective and preventive action (CAPA) implementation.
- Made decisions that affected the production process and finished product based on a strong understanding of the elements surrounding quality assurance and quality control
- Developed a complaint processing procedure that included the following phases: Initiation, device retrieval, lab inspection, failure mode / root cause analysis, CAPA implementation, risk assessment via PFMEA, and effectiveness verification
- Possessed and utilized extensive working knowledge of risk management per ISO 13485, and 21 CFR 820.198 and 820.200
- Ensured that suppliers provided parts, materials, and services that were compliant with CPT's engineering and manufacturing specifications
- Assisted with supplier corrective action requests (SCARs) as needed

Quality Assurance Engineer, Complaint Investigator

January 2018 - March 2019

Cook Medical, Spencer, IN

- Interfaced with appropriate internal/external groups to gather necessary information to conduct timely complaint investigations
- Executed risk assessment as needed during the course of the complaint investigation
- Demonstrated knowledge of formal problem solving tools and appropriate application of those tools
- Performed root cause analysis as necessary (5 whys, Fishbone diagrams, Flowcharting)
- Conducted complaint investigations following Cook's relevant Quality System Procedures
- Supported Cook Medical's Investigations and Quality System Remediation efforts as directed
- Formulated timely, accurate, and defensible complaint investigations while using excellent technical writing skills
- Trained employees on Cook Medical's complaint investigations procedure

Marquette University Biomedical Engineering

Bioelectronics Design Lab, Milwaukee, WI

August 2013 - May 2017

- Medical related world: familiar with functions and design of a biomedical instrumentation system
- Physiological signal analysis: Used electrodes to obtain the EEG of different frequency rhythms in the brain including alpha, beta, delta, and theta
- Designed, built, and tested digital and analog circuits that implemented: timing, heart rate (frequency) measurement, optical isolation, multiplexing, A/D and D/A conversion, physiologic signal bandwidth determination, hardware filters, and tissue impedance characterization
- Gained hands-on experience acquiring and analyzing signals from circuits using an oscilloscope while improving troubleshooting methods

Zip Line Tour Guide

Zip Adventures, Vail, CO

May 2012 - August 2017

- Guided groups of people through a top-rated zip line course
- Sold customers lifetime experiences and memories
- Earned positive reviews on TripAdvisor highlighting visitor's overall experience
- Exhibited professionalism by being fun and outgoing while maintaining participant's safety

EDUCATION

Marquette University - Milwaukee, WI

Bachelor of Science Degree, Biomedical Engineering - Bioelectronics

Graduated: May 2017

AWARDS/RECOGNITION

- Marquette University: Ignatius Scholarship for academic merit 2013, 2014, 2015, 2016
- Marquette University: Magis Leadership Scholarship for meritorious Leadership 2013
- Otero Junior College: Phi Theta Kappa Member (National Honors Society), Inducted in 2013

SKILLS

- Data and information analysis: ability to present high volume spreadsheets using charts, graphs, and pivot tables
- Proficient in Microsoft Office 365 (Excel, PowerPoint, Word, OneNote, Visual Studio C++)
- TrackWise Quality Management System (QMS) Software
- Enterprise resource planning (ERP system) experience in the manufacturing environment.
- Product lifecycle management (PLM)
- PathWise - Technical Writing, Documenting Investigations - 2018
- PathWise - Investigations and CAPA – 2018
- Design, construct, and test digital and analog circuits
- National Instruments LabVIEW (Multisim), software for circuit simulation
- Fluent in English and Spanish, both oral and written
- MATLAB & Simulink
- Salesforce
- SAP

HOBBIES

- Snowboarding, Exercising, Basketball, Yoga