

Michelle Borzick

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Education

Bachelor of Science Mechanical Engineering
Northern Arizona University

Graduation May 2024

Bachelor of Science Biomedical Science
Northern Arizona University

Graduated December 2017

W. L. Gore & Associates Work Experience

Vascular Graft Engineering Technician

August 2023 – Present

- Support Vascular Graft manufacturing teams
- Originate and drive Change Orders and Special Manufacturing Requests
- Drive technical and continuous improvement projects, Sampling Plan Evaluations, Validation Protocols, and CAPA corrective actions.
- Work with cross functional review teams of Quality Assurance, Manufacturing Leadership, Engineering, Product Specialists, Maintenance and Calibration, MOM/PLM Data Specialists, and Regulatory.
- Independently prioritize and manage several projects while maintaining expected timelines.

Vascular Graft Quality Management System Specialist (QMSS)

July 2019 – August 2023

- Support Vascular Graft manufacturing teams with on demand quality and processing questions
- Originate Change Orders, Non-Conformance Reports, Observation Reports, and CAPAs.
- Investigate non-conformances and CAPAs utilizing root cause analysis.
- Train manufacturing and Quality Control operators to the Change Order process as part of their Performance and Development goals.
- Implement and maintain cross-functional communication aids.

Northern Arizona University

Project Manager for Modular Sterile Cleanroom Capstone Project

August 2023 - Present

- Design and build two 12x8 modular hard-walled ISO Class 7 cleanrooms while modifying a smaller ISO Class 7 cleanroom into a gowning room. Utilize structural, thermodynamic, fluid, material, and cost analysis to meet ISO Class 7 standards and budget requirements.
- Lead brainstorming sessions, staff and client meetings, external client and internal team communications.
- Ensure all customer requirements and project deliverables were met by all deadlines.
- Perform computational fluid analysis using hand calculations and Ansys Fluent Solver to determine cleanroom size, filter fan unit placement, wall height/ground gap, and positive pressure maintenance.

Relevant Technical Training

Introduction to Statistics (September 2023), Design of Experiments (October 2023), Process Operational Qualification for Regulated Industry (November 2023), Statistics of Lot Acceptance Sampling Plans (November 2023), Performance Qualification for Regulated Industry (December 2023), PTFE 101 (December 2023)

Other Qualifications

Proficiency in the following programs:

Agile Product Lifecycle Management (PLM), Blue Mountain Regulatory Asset Manager (BMRAM), Camstar, Manufacturing Execution System (MES), Cognos, JMP, Tungsten, Solidworks, Ansys Fluent, Microsoft Office