

NICHOLAS LAGERMAN

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PROFESSIONAL SUMMARY

Biomedical engineer with self-directed project management expertise to conceptualize, design, and test medical devices.

Areas of expertise include:

- Computer-aided design
- Mechanical design
- FDA and ISO regulations
- Verification and validation testing
- Requirement specifications
- Technical documentation
- Medical packaging design and development
- Data analysis

WORK EXPERIENCE

Bayer Radiology (Pittsburgh, PA)

January 2023 – March 2024

Radiology injector and accessory manufacturer, sub-division of Bayer Pharmaceuticals.

R&D Sterile Disposables Engineer

- Led V&V testing for three major projects, ensuring compliance with ISO 11607 standards and regulatory requirements.
- Successfully navigated FDA regulatory pathways, including satisfying requests from an FDA AI Request for a product submitted through a 510(k) submission pathway.
- Assisted in sustainability efforts, resulting in a reduction in plastic use in device packaging and enhanced recyclability of disposables.
- Established strategic partnerships with suppliers to source sustainable, cost-efficient materials for sterile packaging, contributing to operational efficiency and environmental stewardship.
- Supported product supply and manufacturing engineers in transitioning designs for mass production.

IngMar Medical (Pittsburgh, PA)

June 2021 – January 2023

Respiratory simulator manufacturer with 30 employees; \$8.5 million in yearly revenue.

Mechanical Engineer

- Utilized principles from mechanical and biomedical engineering to contribute to the design of respiratory simulators.
- Facilitated the implementation of an Agile project management system for the engineering team.
- Generated comprehensive technical documentation covering various aspects of product development.
- Developed 3D components and drawings using SOLIDWORKS for manufacturing requests and product functionality analysis.

Vascular Bioengineering Laboratory (Pittsburgh, PA)

January 2020 – January 2023

Cardiovascular bioengineering research laboratory at the University of Pittsburgh.

Graduate Researcher

- Executed a project focused on modeling AAA geometry within a perfusion system, supported by the Graduate Engineering Education Scholarship awarded by the University of Pittsburgh's Office of Diversity.
- Maintained meticulous records of design specifications and data in a structured notebook, while also participating in weekly lab meetings to deliver progress updates.
- Authored a research publication detailing the findings of the project, which was published in a university research journal and is slated for publication in the ASAIO Journal by the conclusion of 2024.

EDUCATION

University of Pittsburgh (Pittsburgh, PA)

Bachelor of Science., Bioengineering, Specializing in Biomechanics, 2021

Master of Science, Bioengineering, Medical Product Engineering, 2022

CERTIFICATIONS

Engineer in Training, License #: ET029450

- Passed the Fundamentals of Engineering exam and applied to the State Board for license.

Issued: May 2021

Expires: N/A

ACTIVITIES

Urban Impact Foundation, Volunteer

January 2024 - Present

- Provide weekly tutoring sessions in math and reading for children in 1st through 6th grade.

American Society of Mechanical Engineers (ASME), Member

May 2022 - Present

Biomedical Engineering Society (BMES), Member

August 2020 - Present