Catherine M. Passmore

Senior Consultant, Biomedical Engineering and Sciences

Catherine M. Passmore is a Senior Consultant at Engineering Systems Inc. (ESi) with over nine years of experience in product development and engineering consulting. She is a mechanical engineer specializing in medical and drug-delivery devices, with deep expertise in mechanical design, testing, failure analysis, and digital modeling and simulation.

Catherine applies rigorous engineering methods and inductive reasoning to investigate incidents, assess technical risk, and resolve complex product performance issues. Her consulting work integrates systems engineering, customized testing, predictive modeling, and data-driven analysis to efficiently overcome technical hurdles and inform design decisions. She is experienced across the full product lifecycle—from early-stage feasibility and risk assessment, through late-stage development and post-market failure recovery.

Before joining ESi, Catherine completed more than 100 consulting and R&D projects at Stress Engineering Services, supporting medical device, pharmaceutical, and consumer product companies. She also worked as an R&D engineer at Avanos Medical, developing electromechanical Class II medical devices (De Novo and 510(k) filings) for pain management.

Education

MS, Mechanical Engineering. Case Western Reserve University. 2017

BS, Mechanical Engineering (Magna Cum Laude). Case Western Reserve University. 2016

Positions Held

Engineering Systems Inc., Peachtree Corners, GA

- Senior Consultant, Biomedical Engineering and Sciences (BMES), 2025 – present

Stress Engineering Services Inc., Mason, OH

- Consultant & Technical Account Manager, Consumer Medical Industrial Design & Testing (CMIDT):

Contact Information

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ESi Atlanta

430 Technology Parkway Northwest

Peachtree Corners, GA 30092

Areas of Specialization

- Failure Analysis & Root Cause Investigations
- New Product Development
- Technical Risk Assessment & Management
- Mechanical Design & Evaluation
- Mechanical Testing & Design Verification
- Data Analysis/Data Science
- Systems Engineering
- Computational Modeling & Simulation
- Medical Devices
- Drug Delivery Devices / Combination Devices
- Packaging (CPG and Pharmaceutical) and Consumer Products

- Senior Associate, 2025
- Associate II, 2022 – 2024

Avanos Medical (formerly Halyard Health), Alpharetta, GA

- Senior New Product Development Engineer, Pain Management, 2020 – 2022

Stress Engineering Services Inc., Mason, OH

- Consultant, Consumer Medical Industrial Design & Testing (CMIDT):
  - Associate, 2020
  - Analyst, 2017 – 2019

Case Western Reserve University, Cleveland, OH

- Research Assistant, Biologically Inspired Robotics Laboratory, 2015 – 2016

D&E Machine Co., Lebanon, OH

- Machinist, 2011 – 2012

Continuing Education

- **Plastics Injection Molding** – Stress Engineering Services, Inc., 2024
- **Lean Six Sigma Green Belt** (Course Completion) – Georgia Institute of Technology, 2022
- **Intellectual Property Subject Matter Expert Training** – Avanos Medical, 2021
- **IBM Data Science** – IBM/Coursera, 2020

Professional Affiliations/Honors

Society of Women Engineers

- President – Atlanta Professional Section, 2025 – present
- Member

American Society of Mechanical Engineers

- Member

Quality Science and Education Program, Xavier University

- Mentor, 2020-2021

Project Experience

Failure Analysis & Incident Investigation

- Investigated and identified the root cause of electrical leakage in an electrosurgical instrument in late-stage development; optimized multiple remediation options for electrical isolation with molding simulations, enabling the client to implement a solution and file associated IP.
- Holistically investigated living hinge failures in molded toothpaste caps, evaluating the design, materials, environmental/chemical exposure, and manufacturing processes; identified the cause of the hinge cracking and potential remediation strategies.
- Developed tools to assess failure modes for an on-market metered dose inhaler through performance-based tolerance analyses, which account for material changes over time, temperature, and strain relaxation.
- Supported the CAPA investigation of a surgical stapler with finite element analysis (FEA) simulating edge cases for the usage of the device.

Product Development & Design

- Co-led development of a Class II neuromodulation medical device (De Novo filing), including disposable and capital equipment subsystems. Responsibilities involved test method development and validation, DV planning, risk assessment, design, and manufacturing integration.
- Led a design team to develop a next-generation surgical stapler with an articulating wrist capable of high load and stability requirements. The team utilized innovative mechanical design, predictive modeling, and custom feasibility testing to evaluate and advance the complex design from a concept to a feasible design on an aggressive (<6 months) schedule. The team was able to iterate on this design faster than traditional build-test-fail methods by using calibrated predictive models based on multibody dynamics simulation, FEA, and engineering calculations.
- Spearheaded the development of a physics-based thermal management algorithm for a Class II ultrasonic energy surgical device now commercially available (510 (k)). The algorithm enhanced efficiency by enabling 31% faster vessel transection and decreased device costs.
- Guided R&D organizations through risk-driven design decisions, design control planning, and remediation strategies for product development challenges.

Custom Test Development & Systems Engineering

- Served as systems engineer and lead mechanical test engineer on a high-profile design verification program for an infusion pump combination device.
- Developed and validated platform custom equipment and test methods to characterize wire rope (cable) life and controllability attributes for surgical robotic instruments at the assembly/subassembly level.

- Designed and executed customized test programs for medical devices and packaging systems, including mechanical, thermal, and electromechanical evaluations aligned with ISO/QMS requirements.

Computational Modeling, Data Analysis & Digital Engineering

- Built and applied rigorous computational models of linear and nonlinear components and assemblies to guide design decisions, reduce iteration cycles, and quantify performance sensitivities.
- Used engineering and data science to create data processing tools, determined ethnography KPIs, and developed a minimum viable product (MVP) data pipeline for a large data initiative to extract surgical workflow insights and inform future development opportunities for “smart” surgical devices.

Publications

“3D Printed Mini-Whegs Robot Design and Vibration Analysis”, **C. M. Passmore**, M.S. Thesis, Case Western Reserve University, Cleveland, OH, 2017.

Presentations

“Living Digital Models for Platform Device Development, Faster Speed to Market, and Lifecycle Product Management”, **C. Passmore**, presented at the Parenteral Device Association Miniverse: Medical Devices, Combination Products and Connected Health Conference 2025, Indianapolis, IN, June 25, 2025.

“Failure is Not An Option: Techniques for Understanding Product Reliability Early and Avoiding Career-Limiting Mistakes”, **C. Passmore** and R. States, presented at DeviceTalks Boston Conference 2025, Boston, MA, April 30, 2025.