# OWEN FISCHER

## REGULATORY ENGINEER


### CONTACT

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### SUMMARY


Regulatory engineer with 4 years in design quality and regulatory work for powered Class II infusion and monitoring devices. Plans IEC 60601 and IEC 62304 compliance, writes test summaries for 510(k) submissions and works inside design controls, with clear communication skills and attention to detail.


### SKILLS

- IEC 60601
- IEC 62304
- ISO 14971
- 510(k) Submissions
- Design Controls
- Risk Management
- Standards Matrix
- CAPA
- Communication Skills
- Attention to Detail

### EDUCATION

**Bachelor of Science**

05/2022
University of Utah
Salt Lake City, UT
Biomedical Engineering

### CERTIFICATES

**ISO 14971 Medical Device Risk Management**

09/2023
BSI

### EXPERIENCE

**Regulatory Engineer** 05/2024 - Present

Wasatch Infusion Technologies — Salt Lake City, UT

Developer of ambulatory infusion pumps and patient monitors with 350 employees.

- Plan IEC 60601-1 and 60601-1-2 testing for 3 new pumps, coordinating schedules with 2 accredited test labs.
- Write performance and software sections for **2** 510(k) submissions, both cleared in 2025.
- Review design inputs and verification reports for regulatory requirements in 12 design reviews a year.
- Build a standards matrix covering 45 standards, cutting gap assessment time by 30%.

**Design Quality Engineer** 06/2022 - 04/2024

Bonneville Medical — Draper, UT

Maker of patient monitoring sensors and cables.

- Maintained ISO 14971 risk management files for 6 products through 2 design changes each.
- Led 15 CAPA investigations, closing each within the 60-day target.
- Wrote 30 verification protocols and reports for sensor accuracy and cable durability.
- Updated design history files for 4 products before an FDA inspection with no observations.