Hector Turner

Quality Engineer I, Product and Process Quality

(608) 555-1842 hector.turner@example.com
linkedin.com/example/hectorturner Madison, WI 53703

STRENGTHS

Evidence Based Investigation
Built root cause evidence for nonconformances and CAPA cases. Teams gained clearer decisions when facts felt scattered.

Quiet Process Improvement
Used Lean reviews and process data to reduce variation. Small changes made daily production work smoother.

Supplier Quality Partnership
Reviewed capability data and corrective actions with suppliers. Practical questions often opened better conversations.

Validation Discipline
Connected IQ, OQ, PQ, and V&V records with acceptance evidence. Reviewers could follow each decision.

Cross Functional Communication
Translated statistical findings for engineering, manufacturing, and quality partners. Clear evidence helped groups move forward.

SKILLS

Quality engineering, Validation, CAPA, SCARs, FMEA, DOE, Lean, Six Sigma, Supplier quality, Quality audits, IQ/OQ/PQ, V&V, ISO 9001, ISO 13485, Minitab

LANGUAGES

English — Native

Spanish — Intermediate

SUMMARY

Quality Engineer with two years supporting regulated products and manufacturing operations across validation, nonconformance investigation, supplier controls, audits, and **continuous improvement**. Bachelor's trained mechanical engineer with practical application of ISO 9001, ISO 13485, FDA requirements, **21 CFR Part 820**, **IQ/OQ/PQ**, V&V, CAPA, SCARs, FMEA, DOE, Lean, and Six Sigma. Uses Excel, Minitab, and JMP to turn production and validation data into clear quality decisions. Experience includes molded diagnostic device components, injection molding process controls, supplier qualification, **technical compliance documentation**, and audit preparation. Works closely with R&D, Manufacturing, Quality, Engineering, and supplier teams while managing parallel priorities independently. Brings a calm, evidence based approach to corrective action, risk reduction, and repeatable product performance across regulated manufacturing environments.

EXPERIENCE

Quality Engineer I, Regulated Manufacturing

Alder Medical Components October 2024 - Present Madison, WI

Support lifecycle quality for molded diagnostic device components from design transfer through routine production. Own validation records, deviation investigations, supplier quality activities, risk documentation, audit evidence, and focused improvement work. Partner with Manufacturing, R&D, Quality, Engineering, and external suppliers to protect compliant and repeatable product performance.

- Supported molded diagnostic component transfer through production using lifecycle quality controls and **manufacturing** data.
- Executed **IQ/OQ/PQ** protocols in Minitab, documenting acceptance evidence for validated production processes.
- Investigated nonconformances with **root cause analysis**, CAPA records, and SCARs, then verified corrective actions.
- Updated FMEAs after tooling changes, linking failure risks with controls, sampling, inspection, and verification.
- Qualified suppliers through capability data, change records, incoming trends, and corrective action reviews.
- Prepared **ISO 13485** and **21 CFR Part 820** audit evidence for regulated manufacturing reviews.
- Coordinated **Lean** improvement work that reduced process variation and supported repeatable product performance.

Quality Engineering Research Assistant, Applied Quality Lab

University Applied Quality Lab September 2023 - September 2024 Milwaukee, WI

Supported supervised **quality engineering** studies involving polymer processing, measurement systems, prototype assembly, and supplier quality cases. Applied **statistical analysis**, DOE, FMEA, verification methods, and corrective action planning while presenting findings that supported process standardization and waste reduction.

- Analyzed manufacturing datasets in Excel and JMP, separating common cause variation from actionable signals.
- Built DOE matrices for polymer processing trials and summarized factor effects for follow up experiments.
- Created FMEA records for prototype assembly, connecting failure modes with practical process controls.
- Drafted **verification** protocols and test reports for fixture and measurement system studies.
- Prepared root cause evidence and corrective action plans for simulated CAPA and supplier **quality** cases.
- Presented statistical findings that supported **process standardization** and **waste reduction** decisions.

MY CAREER

- Quality Engineer I, Regulated Manufacturing at Alder Medical Components (1.9 Years)
- Quality Engineering Research Assistant, Applied Quality Lab at University Applied Quality Lab (1 Years)

PROJECTS

Polymer Processing DOE Study 2024

Built a structured DOE study for polymer processing trials, helping reviewers see factor effects, follow up needs, and practical paths toward more stable manufacturing performance.

Diagnostic Component Validation Framework 2025

Organized validation evidence across IQ, OQ, PQ, and V&V activities, giving cross functional reviewers a clearer path from process requirements through documented acceptance.

LEADERSHIP & AWARDS

- Earned ASQ Certified Quality Improvement Associate recognition in 2025.
- Completed Lean Six Sigma Green Belt certification in 2025.
- Presented applied statistical findings that supported process standardization and waste reduction.

EDUCATION

Bachelor's Degree in Mechanical Engineering

University of Wisconsin-Milwaukee GPA: 4.0 2024 Milwaukee, WI

Coursework: *Quality engineering, statistical methods, manufacturing processes, design of experiments*

CERTIFICATIONS

- ASQ Certified Quality Improvement Associate 2025
- Lean Six Sigma Green Belt 2025

TECHNICAL SKILLS

- **Quality Systems:** ISO 9001, ISO 13485, 21 CFR Part 820
- **Validation Methods:** IQ, OQ, PQ
- **Verification Practices:** V&V, validation protocols, validation reports
- **Corrective Action:** CAPA, SCARs, root cause analysis
- **Risk Management:** FMEA, process controls, risk review
- **Statistical Analysis:** Minitab, JMP, Excel
- **Process Improvement:** Lean, Six Sigma, waste reduction
- **Manufacturing Processes:** Injection molding, process standardization, production controls
- **Supplier Quality:** Supplier qualification, capability data, corrective action reviews
- **Regulatory Documentation:** Design History Files, product certifications, audit evidence

PROFESSIONAL AFFILIATIONS

- ASQ community participant with interest in quality systems and continuous improvement.
- University applied quality lab contributor focused on manufacturing data and validation methods.

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST