Thao Walton

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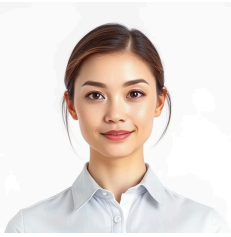

SUMMARY

Principal level manufacturing engineer with eight years of progressively responsible experience delivering Manufacturing Execution System capabilities in regulated medical production environments. Leads architecture, workflow definition, **user interface configuration**, ERP integration, **production record systems**, digital work instructions, and manufacturing data models from concept through validated operation. Directs GMP and **21 CFR Part 11** compliance activities, risk based testing, audit controls, and **IQ/OQ/PQ** protocols for production lines. Uses DMAIC, system metrics, shop floor observations, and cross functional collaboration to improve traceability, inventory control, cost performance, and operational reliability. Communicates technical findings through clear ROI, cost, production record, and compliance analyses for operations and quality leaders. Ready to contribute practical engineering judgment, disciplined validation, and steady partnership across manufacturing, quality, and systems teams.

EXPERIENCE

Principal Manufacturing Systems Engineer

March 2024 - Present

Northfield Life Sciences

Worcester, MA

Owns MES architecture, validated production operations, compliance controls, and optimization programs for regulated manufacturing lines. Provides technical direction across operations, quality, and systems stakeholders while connecting business priorities with reliable digital execution.

- Aligned **MES architecture** with GMP traceability requirements across regulated production **workflows**
- Configured operator interfaces and ERP integrations for multiple production lines
- Directed **IQ/OQ/PQ** releases with risk based test steps and approval evidence
- Established **21 CFR Part 11** controls for records, access, and **audit trails**
- Applied DMAIC and **MES** metrics to remove execution bottlenecks on production lines
- Presented cost, ROI, inventory, and production record findings to quality leaders

Senior Manufacturing Systems Engineer

June 2021 - February 2024

Beacon Surgical Technologies

Lowell, MA

Designed and validated MES workflows supporting surgical device production, electronic history records, material transactions, and quality checks. Partnered with manufacturing and quality teams to convert approved procedures into controlled digital execution.

- Connected MES **data models** with production instructions, quality checks, and history records
- Integrated **ERP** material and order transactions across manufacturing and quality functions
- Executed controlled **validation** testing with requirements, evidence, deviations, and approvals
- Converted approved procedures into digital **work instructions** and **process maps**
- Monitored production exceptions and system performance before validated enhancements
- Used **DMAIC** investigations to correct workflow failures and strengthen controls

Manufacturing Systems Engineer

July 2019 - May 2021

Granite Biomedical Systems

Cambridge, MA

Configured MES interfaces, production workflows, inventory analysis, and compliance documentation for biomedical manufacturing. Supported line qualification, operator feedback cycles, audit preparation, and controlled changes within production systems.

- Configured MES interfaces supporting component traceability and electronic production records
- Built inventory and production record analyses for process and cost decisions
- Supported **IQ/OQ/PQ** execution for line specific MES functions and discrepancies
- Maintained **SOP** aligned instructions, **process maps**, and configuration records
- Translated operator feedback into requirements for validated user interface improvements
- Assembled traceability, configuration, and test evidence for compliance **audits**

Mechanical Engineer

June 2018 - June 2019

HarborPoint Instruments

Springfield, MA

Supported manufacturing studies, process documentation, cost analysis, and early digital production record requirements. Connected engineering observations with inventory data and production evidence to guide practical improvements and follow up.

- Compared equipment and process alternatives through cost and **ROI** analysis
- Applied DMAIC to material flow and production record accuracy problems

- Created engineering **work instructions** for controlled production changes
- Coordinated digital production record requirements with systems personnel
- Reviewed inventory and production data after implementation changes
- Documented follow up actions from engineering and production observations

PROJECTS

Validated MES Traceability Program 2025

Led a focused traceability improvement program linking production records, quality evidence, audit controls, and operator workflows. Clarified requirements, strengthened validation evidence, and improved confidence in regulated digital execution.

Production Data Optimization Study 2023

Analyzed MES metrics, inventory records, production exceptions, and ROI inputs to identify practical optimization opportunities. Applied DMAIC thinking and stakeholder review to prioritize sustainable system improvements.

LEADERSHIP & AWARDS

- Digital Manufacturing Excellence Recognition, Northfield Life Sciences, 2025
- MES Validation Working Group Lead, Northfield Life Sciences, 2024 - Present
- Cross Functional Compliance Contribution Recognition, Beacon Surgical Technologies, 2023

EDUCATION

Bachelor's Degree in Mechanical Engineering 2018

University of Massachusetts Lowell GPA: 0 *Lowell, MA*

Coursework: *Manufacturing systems, Mechanical design, Production operations, Engineering analysis*

CERTIFICATIONS

- Lean Six Sigma Green Belt 2021
- Computer System Validation and IQ/OQ/PQ Continuing Education 2023
- GMP and 21 CFR Part 11 Compliance Training 2024

TECHNICAL SKILLS

- **MES Platforms:** MES architecture, MES workflows, production record systems
- **ERP Integration:** ERP transactions, material data, order data
- **Validation Methods:** IQ/OQ/PQ, computer system validation, risk based testing
- **Regulatory Compliance:** GMP, 21 CFR Part 11, audit controls
- **Manufacturing Documentation:** SOPs, digital work instructions, process maps
- **Quality Systems:** Quality checks, deviations, approvals
- **Data and Records:** Manufacturing data models, electronic records, traceability
- **Operational Improvement:** DMAIC, system optimization, corrective controls
- **Business Analysis:** ROI analysis, cost reduction, inventory control
- **Testing and Release:** Requirements testing, acceptance evidence, qualification packages

SKILLS

- MES architecture
- MES workflows
- ERP integration
- GMP
- 21 CFR Part 11
- IQ/OQ/PQ
- DMAIC
- Digital manufacturing
- SOP
- Process maps
- Production record systems
- Inventory control
- ROI analysis
- Cost reduction
- Regulatory testing

PROFESSIONAL AFFILIATIONS

- MES Validation Working Group, Lead, 2024 - Present
- Manufacturing and Quality Systems Collaboration Forum, Participant, 2021 - Present

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST