

Principal Manufacturing Engineer, Manufacturing Execution Systems

STRENGTHS

Built qualification packages with clear test evidence, helping production and quality teams gain confidence in MES releases.

Used shop floor observations and DMAIC reviews to trace workflow failures back to useful corrective actions.

Translated operator concerns into validated system changes, becoming a dependable partner for manufacturing and quality peers.

Established access, audit trail, and electronic record controls that supported regulated production without slowing daily work.

Connected cost, ROI, inventory, and production record findings with decisions leaders could act on quickly.

Cost reduction Regulatory testing

English Native

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.

- Presented cost, ROI, inventory, and production record findings to quality leaders

- Used **DMAIC** investigations to correct workflow failures and strengthen controls

- Assembled traceability, configuration, and test evidence for compliance **audits**

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MY CAREER



- Principal Manufacturing Systems Engineer at Northfield Life Sciences (2.5 Years)
- Senior Manufacturing Systems Engineer at Beacon Surgical Technologies (2.7 Years)
- Manufacturing Systems Engineer at Granite Biomedical Systems (1.8 Years)
- Mechanical Engineer at HarborPoint Instruments (1 Years)

- 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

University of Massachusetts Lowell 🎓 GPA: 0 📅 2018 📍 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

PROFESSIONAL AFFILIATIONS

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

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST