# Abraham Hartman

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## SUMMARY

Senior Manufacturing Engineer with more than eight years improving regulated medical device processes, equipment, validation programs, and new product readiness. Leads complex initiatives that balance safety, Quality System requirements, GMP, technical risk, capital planning, schedules, and supply continuity. Owns process investigations, characterization studies, **design of experiments**, qualification, validation, statistical analysis, risk assessment, change control, and **structured problem solving**. Partners with Operations, Quality, R&D, EHS, Maintenance, Automation, Materials, Product Engineering, Procurement, Finance, and suppliers to convert business needs into capable manufacturing solutions. Provides technical direction and mentoring for engineers and technicians without formal supervisory authority. Applies **Lean Manufacturing Principles**, **design for manufacturability**, lifecycle management, and data driven decisions to improve quality, yield, reliability, flexibility, cost, and delivery.

## EXPERIENCE

### Senior Manufacturing Engineer, Regulated Surgical Device Production

May 2023 - Present

Northstar Surgical Technologies *Minneapolis, MN*

Leads cross functional engineering programs for regulated surgical device production, owning process investigations, equipment capability, validation strategy, capital planning, technical documentation, and mentoring across manufacturing operations.

- Integrated equipment capability, GMP, EHS, **quality** controls, and supply needs into executable project plans.
- Resolved recurring process issues through **structured problem solving**, **statistical analysis**, and risk based corrective actions.
- Built **project charters**, schedules, capital estimates, and **technical justifications** for manufacturing investments.
- Defined characterization studies and **design of experiments** that established operating windows for validation decisions.
- Represented process and equipment expertise during audits, transfers, change reviews, and technical decisions.
- Mentored engineers and technicians on validation planning, troubleshooting, data interpretation, and controlled change practices.

### Manufacturing Engineer III, Precision Medical Components

February 2021 - April 2023

Lakefront Medical Components *St. Paul, MN*

Owned validated processes and equipment for precision medical components, leading qualifications, capacity work, new product introduction readiness, risk assessments, change control, and cross functional technical reporting.

- Led **equipment** qualifications for **capacity** additions, aligning protocols, acceptance criteria, sampling, and final reports.
- Applied Lean methods to workflow constraints, recurring defects, and equipment **reliability** concerns in controlled production.
- Coordinated new product readiness with **R&D**, Materials, Automation, suppliers, and **Product Engineering** teams.
- Translated design requirements into manufacturing methods, documented controls, and practical production workflows.
- Built risk assessments and **change control** packages for equipment modifications and material changes.
- Prepared schedules, engineering reports, cost estimates, and stakeholder updates for capacity and lifecycle decisions.

### Manufacturing Engineer II, Disposable Medical Products

June 2019 - January 2021

Prairie Biomedical Manufacturing *Madison, WI*

Supported validated disposable medical product processes, expanding ownership of equipment performance, statistical studies, qualification protocols, continuous improvement, documentation, and design for manufacturability.

- Characterized manufacturing variation through process studies and statistical analysis, informing operating parameter recommendations.
- Executed **qualification** protocols for tooling and equipment changes under **Quality System**, GMP, and change control procedures.
- Investigated production defects with technicians and quality engineers using **structured problem solving** tools.
- Identified assembly and process risks during **design for manufacturability** reviews before routine production changes.
- Simplified material movement and standard work through Lean workplace improvements without weakening **safety** controls.
- Documented equipment performance, engineering evidence, and **continuous improvement** actions for validated production processes.

### Manufacturing Engineer, Regulated Healthcare Products

July 2017 - May 2019

Midwest Health Products *Milwaukee, WI*

Supported **manufacturing engineering** for regulated healthcare products, building practical capability in process documentation, equipment troubleshooting, **validation** execution, data analysis, supplier coordination, and production support.

- Analyzed **manufacturing** data to evaluate process stability and equipment performance for engineering review.
- Executed approved **engineering** trials and qualification activities under senior guidance, maintaining controlled records.
- Updated work instructions, drawings, and process documentation through formal **change control**.
- Identified flow, organization, and operator usability improvements through basic Lean manufacturing observations.
- Coordinated equipment issue follow up with maintenance, **operations**, quality, and suppliers.
- Documented deviations and technical findings for quality review and disposition decisions.

## PROJECTS

**Capacity Expansion and Equipment Qualification** 2024

Led a regulated capacity initiative that connected equipment qualification, process characterization, capital planning, risk assessment, and production readiness. Structured technical evidence helped stakeholders approve implementation with controlled documentation and clear ownership.

**New Product Manufacturing Readiness** 2022

Coordinated manufacturing readiness for a medical product transition by translating design requirements into process controls, qualification activities, supplier actions, and documented workflows that supported compliant production.

## LEADERSHIP & AWARDS

- Lean Six Sigma Green Belt, applied process improvement methods across regulated manufacturing operations.
- ASQ Certified Quality Improvement Associate, recognized for quality systems knowledge and structured improvement practice.
- Technical mentor for manufacturing engineers and technicians, providing direction during validation, troubleshooting, and change initiatives.

## EDUCATION

**Bachelor of Science in Mechanical Engineering** 2017

University of Wisconsin Milwaukee GPA: 0 *Milwaukee, WI*

***Coursework:*** *Manufacturing engineering, statistics, materials science, mechanical design*

## CERTIFICATIONS

- Lean Six Sigma Green Belt 2022
- ASQ Certified Quality Improvement Associate 2020

## TECHNICAL SKILLS

- **Manufacturing Engineering:** Process engineering, MSAT, manufacturing science
- **Validation and Qualification:** Process validation, equipment qualification, validation protocols
- **Statistical Methods:** Statistical analysis, design of experiments, process characterization
- **Quality Systems:** GMP, Quality System requirements, controlled documentation
- **Risk and Problem Solving:** Risk assessment, structured problem solving, root cause analysis
- **Lean Methods:** Lean Manufacturing Principles, continuous improvement, standard work
- **Project Planning:** Project charters, implementation plans, project schedules
- **Capital Engineering:** Capital requests, financial estimates, technical justifications
- **Manufacturing Readiness:** New product introduction, capacity planning, manufacturing transfers
- **Process Documentation:** Change control, technical reports, work instructions
- **Design and Process Development:** Design for manufacturability, operating windows, process controls
- **Cross Functional Operations:** Supplier coordination, maintenance, automation

## SKILLS

- Manufacturing Engineering
- Process Validation
- Equipment Qualification
- Statistical Analysis
- Risk Management
- Structured Problem Solving
- Lean Manufacturing
- GMP
- Quality Systems
- Design for Manufacturability
- New Product Introduction
- Change Control
- Project Engineering
- Capacity Planning
- Technical Reporting

## PROFESSIONAL AFFILIATIONS

- Cross functional manufacturing engineering partner across Operations, Quality, R&D, EHS, Maintenance, and Automation.
- Technical liaison for Materials, Product Engineering, Procurement, Finance, suppliers, and production stakeholders.

## LANGUAGES

- English (Native)
- Spanish (Intermediate)

## ADDITIONAL INFORMATION

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

## REFERENCES

AVAILABLE ON REQUEST