# Christopher R. Staub

Driving regulated medical manufacturing forward with data-driven validation, lean thinking, and collaborative execution.

**Manufacturing Engineer | Process Optimization | Digital Integration** 

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#### SUMMARY

Manufacturing Engineer with proven expertise in process validation, root cause analysis, and lean improvement within regulated medical device environments. Blending hands-on engineering with modern development tools, I design and integrate digital solutions that enhance production efficiency and data reliability. Recently led the modernization of the Access Point Vascular (APV) mobile application using React Native, TypeScript, and AWS serverless architecture, demonstrating a strong bridge between manufacturing operations and software-driven process optimization.

#### **EXPERIENCE**

# **Manufacturing Engineer II**

Jun 2024 - Present

Olympus Medical and Surgical · Brooklyn Park, MN

- Own manufacturing engineering support for medical device production, maintaining 98.2% process stability and achieving 15% throughput improvement through targeted optimization initiatives.
- Develop and execute IQ/OQ/PQ validations for new product introductions, completing 8 validation packages in 2024 with 100% FDA and ISO 13485 compliance rate.
- Partner with R&D, Quality, and Supply Chain teams to resolve production issues, reducing defect rates by ~22% and cutting resolution time by 40% through structured root cause analysis and CAPA deployment.
- Author and maintain SOPs, work instructions, and equipment protocols to standardize execution and ensure audit readiness.
- Advance Lean and Six Sigma initiatives that improved yield by ~10%, reduced scrap costs by ~\$65K annually, and cut operating costs by ~10% while scaling tooling and equipment capabilities.
- Coordinated cross-functional teams across Quality, Design, and Production to implement process improvements and validation activities, ensuring ontime completion of CAPA and CO actions.

# **Manufacturing Engineer II**

Jun 2022 – Jun 2024

Minnetronix Medical · Saint Paul, MN

- Designed and executed IQ/OQ/PQ strategies for manufacturing processes, equipment, and tooling to satisfy regulatory scrutiny.
- Identified waste and cost drivers, delivering targeted process optimizations that elevated yield and cycle efficiency.
- Led root cause investigations across cross-functional teams, driving corrective actions that prevented repeat quality events.
- Partnered with Quality on CAPA execution, reinforcing a culture of traceability, documentation accuracy, and continuous improvement.

# **Senior Manufacturing Engineering Technician**

Minnetronix Medical · Saint Paul, MN

Jun 2017 – Jun 2022

- Delivered hands-on technical expertise that kept production lines running, troubleshooting complex issues alongside engineers.
- Performed preventive maintenance, calibration, and repairs to uphold equipment capability and regulatory compliance.
- Maintained meticulous manufacturing documentation and supported Lean/Six Sigma events to unlock productivity gains.

# **Manufacturing Technician IV**

Aug 2013 - Jun 2017

Boston Scientific · Arden Hills, MN

- Executed SOP-driven manufacturing activities while monitoring equipment performance and coordinating timely maintenance.
- Spearheaded continuous improvement opportunities that enhanced productivity and material utilization.
- Documented production records with precision and mentored junior technicians on quality and safety expectations.

# **Technical Compliance Analyst**

Aug 2007 – Aug 2013

Compass Airlines · Minneapolis, MN

- Interpreted FAA, EASA, and international regulations to lead compliance programs across an airline maintenance organization.
- Conducted internal audits, maintained controlled documentation, and stewarded Safety Management System initiatives.
- Facilitated regulator engagements, supported incident investigations, and drove preventive actions post-review.

### **Aviation Maintenance Technician**

Jan 2000 - Aug 2007

Champion Air · Bloomington, MN

- Conducted scheduled and unscheduled aircraft maintenance, inspections, and repairs in accordance with regulatory standards.
- Diagnosed system discrepancies using technical publications and instrumentation, executing repairs that restored airworthiness.
- Managed tooling and parts inventory to keep heavy maintenance projects on schedule.

# **EDUCATION**

## **Frederick Community College**

Frederick, MD · Aviation Maintenance Technician Certificate · May 1998

# **CERTIFICATIONS**

IPC 610 Cable & Wire Harness Assemblies (Feb 2021)

SolidWorks Mechanical Design (Oct 2021)

SolidWorks CAD Essentials (Sep 2019)

RJG Systematic Molding – Silicone Rubber (Mar 2016)

Arburg Injection Molding Training (Feb 2016)

## **SELECTED PROJECTS**

# Access Point Vascular (APV) — Mobile App Redevelopment

Side project with team peers • 2024 - Present

- Collaborating with cross-disciplinary teammates to transition APV's legacy
   Angular mobile app to a modern **React Native** experience for nurse and
   manager users.
- Led complete rewrite from Angular → React Native (Expo SDK 52), refactoring authentication and navigation flows.
- Implemented secure AWS Cognito login and integrated REST API endpoints via AWS Lambda + PostgreSQL RDS.
- Introduced **TypeScript** across all modules, improving type safety, reliability, and maintainability.
- Set up GitHub Actions for CI/CD pipelines and automated Android build deployments.
- Achieved 100% React Native test coverage (74/74 tests passing) with comprehensive mocking system and optimized Jest configuration.
- Established TypeScript strict mode and comprehensive code quality standards with ESLint, Prettier, and Husky pre-commit hooks.

**Tech Stack:** React Native (Expo 52) • TypeScript • AWS Lambda • Cognito • PostgreSQL RDS • GitHub Actions

Outcome: Improved team velocity and reduced build friction through standardized code patterns and automated pipelines.

### **SKILLS**

# Core Manufacturing & Process Engineering

Process validation (IQ/OQ/PQ) • Lean Manufacturing & Six Sigma • Root Cause & CAPA • Equipment Qualification • Regulatory Compliance (FDA, ISO 13485)

### **Design & Technical Tools**

SolidWorks • AutoCAD • Minitab • Power BI • SAP • Cognex VisionPro OCR • PLC Integration Fundamentals

#### **Data & Automation**

Python • SQL • PostgreSQL •
Power BI • AWS Lambda • Docker •
REST API Integration

#### **Digital Tools & Development**

TypeScript • JavaScript • React Native (Expo 52) • Node.js • AWS (Lambda, Cognito, RDS) • Docker • GitHub Actions • Python Automation • REST API Integration

#### **Certifications**

SolidWorks CSWA • Lean Six Sigma Green Belt (in progress) • IPC-7711/7721 • Injection Molding Process • Cleanroom Manufacturing

Combining data analysis, process automation, and app development to enhance manufacturing efficiency and traceability.

## PROFESSIONAL INTERESTS

Smart manufacturing, process automation, mobile tools for regulated operations, and cloud-based validation systems.