Christopher R. Staub

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SUMMARY

Results-driven Manufacturing Engineer with a proven track record of optimizing complex medical device manufacturing processes through data-driven problem-solving, cross-functional collaboration, and regulatory compliance expertise. Skilled in process validation (IQ/OQ/PQ), Lean/Six Sigma implementation, and root cause analysis to drive quality, reduce waste, and improve operational efficiency.

EXPERIENCE

Manufacturing Engineer II

Olympus Medical and Surgical, Brooklyn Park, MN

June 2024 - Present

- Lead manufacturing engineering support for medical device production, ensuring process stability and driving continuous improvement initiatives.
- Develop and execute process validations (IQ, OQ, PQ), supporting new product introductions and sustaining engineering efforts in compliance with regulatory standards (FDA, ISO 13485).
- Partner cross-functionally with R&D, Quality, and Supply Chain teams to identify, investigate, and resolve production issues through structured root cause analysis and implementation of corrective/preventive actions (CAPA).
- Create and maintain manufacturing documentation, including SOPs, work instructions, and equipment protocols to ensure consistent execution and regulatory compliance.
- Identify and implement Lean and Six Sigma strategies to improve yield, reduce scrap, and increase throughput, contributing to cost reduction and operational excellence goals.
- Support equipment and tooling specification, procurement, and qualification to scale up production.

Manufacturing Engineer II

Minnetronix Medical, Saint Paul, MN

June 2017 - June 2024

- Designed and executed validation protocols (IQ, OQ, PQ) for manufacturing processes, equipment, and tooling, ensuring compliance with regulatory standards.
- Identified and implemented process optimization initiatives, resulting in waste reduction and cost savings.
- Conducted root cause analysis investigations to identify underlying causes of manufacturing issues, collaborating with cross-functional teams to implement effective corrective actions and prevent recurrence.
- Collaborated with the Quality team to address and resolve manufacturing-related quality issues, implementing
 corrective and preventive actions (CAPAs) and driving process improvements.

Senior Manufacturing Engineering Technician

- Provided technical expertise and support to manufacturing processes, equipment, and tooling, collaborating with engineers to troubleshoot and resolve complex manufacturing issues.
- Conducted preventive maintenance, calibration, and repair activities on manufacturing equipment to ensure optimal performance and compliance with regulatory requirements.
- Maintained accurate and up-to-date manufacturing documentation, including work instructions, standard operating procedures (SOPs), and equipment logs, ensuring compliance with regulatory standards.
- Actively participated in Lean Manufacturing and Six Sigma projects, driving process improvements, waste reduction, and cost savings.

Manufacturing Technician IV

Boston Scientific, Arden Hills, MN

August 2013 - June 2017

- Executed manufacturing processes in accordance with SOPs and work instructions, ensuring efficient production and adherence to quality standards.
- Operated and maintained manufacturing equipment, conducted routine maintenance activities, and troubleshooting to minimize downtime and optimize productivity.
- Identified opportunities for process improvements, waste reduction, and productivity enhancements, collaborating with cross-functional teams to implement changes and optimize operations.
- Maintained accurate and up-to-date production records, including batch records, logbooks, and quality control
 documents, with meticulous attention to detail.
- Assisted in troubleshooting and resolving manufacturing issues, conducting root cause analysis, and implementing corrective actions to prevent recurrence.
- Provided training and guidance to junior technicians, ensuring their understanding of manufacturing processes, safety protocols, and quality requirements.

Technical Compliance Analyst

Compass Airlines, Minneapolis, MN

August 2007 - August 2013

Ensured regulatory compliance by interpreting and analyzing aviation regulations, such as FAA, EASA, and other
relevant authorities, and implementing compliance measures across all operational areas.

- Conducted regular internal audits and assessments to verify compliance with regulatory standards and company policies, identifying areas for improvement and recommending corrective actions.
- Maintained accurate and up-to-date documentation related to regulatory compliance, including manuals, policies, procedures, and records, ensuring proper documentation control and record retention.
- Assisted in the implementation and maintenance of the airline's Safety Management System (SMS), collaborating with cross-functional teams to identify hazards, assess risks, and develop mitigation strategies for enhanced safety performance.
- Provided technical expertise in incident and accident investigations, supporting root cause analysis and the development of preventive measures to mitigate similar incidents in the future.
- Served as a point of contact with regulatory authorities during audits and inspections, facilitating communication, providing requested documentation, and assisting in addressing findings or inquiries.

Champion Air, Bloomington, MN Aviation Maintenance Technician

January 2000 - August 2007

- Conducted scheduled and unscheduled maintenance tasks on aircraft, including inspections, troubleshooting, component replacements, and repairs, ensuring compliance with regulatory requirements.
- Completed accurate and thorough maintenance documentation, including work orders, maintenance records, and inspection reports, to ensure compliance with aviation regulations and company policies.
- Utilized diagnostic equipment, technical manuals, and expertise to identify and resolve aircraft system malfunctions and discrepancies, conducting comprehensive troubleshooting to pinpoint root causes and implement effective repairs.
- Performed routine inspections and maintenance tasks based on aircraft manufacturer's recommendations and regulatory requirements, ensuring optimal aircraft performance and airworthiness through fluid checks, component lubrication, and system functional tests.
- Conducted repairs and overhauls on aircraft components, such as engines, landing gear, electrical systems, and avionics, following approved procedures, service bulletins, and technical publications to ensure proper repairs and restoration of component functionality.
- Managed inventory levels of aircraft parts, consumables, and tools, coordinating with the Supply Chain department to
 order and receive necessary supplies in a timely manner, while accurately documenting parts usage and adhering to
 proper storage practices.

EDUCATION

Frederick Community College, Aviation Maintenance Technician 2-year certificate CERTIFICATIONS	Frederick, MD May,1998
SolidWorks Mechanical Design Certificate	October 2021
SolidWorks CAD essentials Certificate	September 2019
RJG Systematic Molding Silicone Rubber	March 2016
Arburg Injection Molding Training	February 2016

SKILLS

CAD Design (SolidWorks)
Injection Molding (Silicone Rubber)
Application Development (JavaScript, TypeScript, React Native)
Al Integration (RAG systems, LLM applications)