

MANAGER, QUALITY ENGINEERING

Executive Summary

With over 14 years of experience in the fields of Class II and III medical device manufacturing, molecular diagnostics, and biotechnology; the last 8 of which have been managing engineers, technicians as well as supervisors, I bring strong technical leadership to any organization. I have a solid background in data analysis and statistics that I use to develop and continuously improve all aspects of the manufacturing process with a focus on efficiency and consistency.

Core Qualifications

ProEngineer/CREO, MiniTab, MS Office Suite, MS Project, MS Visio, Injection Molding, Trackwise, Catsweb

Professional Experience

Manager, Quality Engineering

April 2014 to Current Company Name 1/4 City , State

- Manage the Quality Engineering Team, the Complaints Department, and the Metrology Department at Alcon's Class II and Class III medical device manufacturing facility.
- Responsible for improving site compliance and reducing recurring deviations through NCR Investigations and CAPA implementation.
- Investigate customer complaints and interface with regulatory groups to provide feedback to doctors.
- Direct the teams to provide Calibration support for two medical device-manufacturing facilities.
- Responsible for setting priorities, providing direction, coaching, motivation, mentoring and development of both exempt and non-exempt direct reports.

Senior Engineer II (Managed Process Engineering and Automation Groups)

March 2011 to April 2014 Company Name 1/4 City , State

- Process Control Lead Responsibilities added September 2013.
- Managed the Process Engineering and Automation Groups at Alcon's Class II/III surgically implantable optic device and delivery systems manufacturing facility.
- Responsible for setting priorities, providing direction, coaching, motivation, mentoring and development of both exempt and non-exempt direct reports.
- Responsible for the engineering activities and support related to all aspects of the manufacturing process including: Injection Molding, Assembly, Curing, CNC machining, Chemical Processing, and Inspection.
- Applied technical expertise to improve yield of AcrySof® manufacturing.
- Helped to reduce the particulate reject rate for Wavefront product by 50%.
- Reduced dimensional failures from 5% to to <0.3% and=" saved=" the=" facility=" ~\$1.4m=" in=" labor=" and=" materials=">
- Led the implementation of multiple automation projects, each of which have improved quality, increased capacity, and reduced cycle time with paybacks realized between 1 and 3 years.
- Managed departmental budget, automation budget as well as capital projects to achieve savings of at least \$100k without sacrificing service levels.

Senior Engineer I

September 2007 to March 2011 Company Name 1/4 City , State

- Supervised the Drafting group, Custom Tool Production, Milling, Injection Molding, and Clean Room Engineering Support staff for both Class II and Class III medical device manufacturing.
- Set priorities, provided direction, and supervision to direct reports.
- Specified, developed, procured, and validated addition of vision inspection systems to the automated milling machines and improved cut quality and consistency of AcrySof® Single-Piece IOLs.
- Provided technical support for the injection molding process, assembly, curing, machining, and clean room operations.

Process Engineer II

February 2005 to September 2007 Company Name 1/4 City , State

- Engineer responsible for process development and improvement at Alcon's Class II/III medical device manufacturing site.
- Designed, built, validated, and implemented the next generation automated milling machines for use in AcrySof Single-Piece IOL manufacturing.
- Increased output in AcrySof Single-Piece IOL milling by more than 25% while not impacting quality through an iterative process of adjusting key parameters and verifying impact on cycle time and product quality.
- Designed, built, tested, and validated the prototype packaging and labeling workstation. Evaluated prototype for ergonomics and work flow with the help of production personnel. Modified the design accordingly and built, and validating the remaining 23 workstations. Validated improvements to the software after initial release. The resultant stations prevent packaging failures from getting out into the field.
- Developed and analyzed proof of concept models to evaluate manufacturing improvements using Pro/E prior to implementation.
- Set priorities, provided direction, and supervision to one direct report

Research Engineer

September 2003 to February 2005 Company Name 1/4 City , State

- Designed, built, and tested an automated reagent packaging system to improve lot homogeneity and increase manufacturing throughput of Lab-in-a-tube (LIATTM) technology.
- Created original Labview programs and amended existing programs to improve functionality for numerous test fixtures and automated systems.
- Designed and built a novel spotting-device for producing protein microarrays compatible with a 96-well microplate format for high throughput applications.
- Programmed Labview spotting routine for the protein microarray spotting-device.
- Tested numerous concepts to develop design parameters of the LIAT analyzer (ie.tube tensioning, segment length, tube diameter).
- Assisted in the preparation of patent applications and responses to examiner's actions.

Patent Examiner

July 2002 to September 2003 Company Name i¼ City , State

- Reviewed patent applications for compliance with the United States Code and determined novelty of invention.
- Composed reviews of applications and communicated with applicants to assist them through the patent process.

Graduate Research Assistant

September 2000 to July 2002 Company Name i¼ City , State

- Designed, built, and tested an apparatus for producing sol-gel based DNA hybridization arrays.
- Developed and troubleshoot instrumentation for controlling pad size and placement within an array.
- Developed a sol-gel production protocol to provide specific pore size and flow characteristics for use in capillary chromatography.
- Created aerogel samples, conducted compression testing, and measured the internal surface area.

Education

Master of Science : Mechanical Engineering UNIVERSITY OF VIRGINIA i¼ City , State

Bachelor of Arts : Physics and Biology COLBY COLLEGE i¼ City , State

Skills

Manufacturing, Assembly, Automation, Budget, Calibration, CNC, Coaching, MS Office Suite, MS Project, MS Visio, MiniTab, Stat Graphics, Process Engineering, Manufacturing process development and improvement, Manufacturing yield improvement, CIP, Pro Engineer/CREO

Awards and Memberships

- Alcon Special Achievement Award
- Graduated with distinction in Physics
- Member of Sigma Pi Sigma, Physics student honor society